K080462

1 of 2

MAY 13 2008

Medtronic Sofamor Danek
PROGENIX™ DBM Putty
510(k) Summary
February 2008

I. **Company:** **Medtronic Sofamor Danek USA**
1800 Pyramid Place
Memphis, TN 38132
Telephone: (901) 396-3133
Fax: (901) 346-9738

Contact: **Michelle Obenauer**
Regulatory Affairs Supervisor

II.

Proposed Proprietary Trade Name:	PROGENIX™ DBM Putty
Classification Name:	Bone Void Filler
Product Code:	NUN
Regulation No.:	872.3930

III. **Product Description/Purpose of Application**

PROGENIX™ DBM Putty contains human demineralized bone matrix (DBM) in a biocompatible carrier. The carrier is a mixture of bovine collagen with a natural polysaccharide (sodium alginate). The components are mixed in phosphate buffered saline to achieve a flowable or moldable consistency. All DBM used in the preparation of PROGENIX™ DBM Putty must induce bone formation when evaluated in a validated athymic nude rat assay. Although, findings from an animal model are not necessarily predictive of human clinical results.

PROGENIX™ DBM Putty is a single use product intended for use in the oralmaxillofacial region. Additionally, this product is not designed to impart any mechanical strength to the surgical site. PROGENIX™ DBM Putty is provided in ready-to-use malleable forms that may be molded or manipulated by the surgeon into various shapes. This product has been shown to be osteoconductive as well as osteoinductive in an athymic rat assay, allowing for bony ingrowth across the graft site while resorbing at a rate consistent with bony healing.

The purpose of this 510(k) application is to introduce PROGENIX™ DBM Putty into the market for the oralmaxillofacial applications listed on the Indications for Use Form.

IV. Indications

PROGENIX™ DBM Putty is intended for the augmentation of deficient maxillary and mandibular alveolar ridges and the treatment of oralmaxillofacial and dental intraosseous defects including but not limited to:

Ridge augmentation
Filling of cystic defect
Filling of extraction sites
Filling of lesions of periodontal origin
Craniofacial augmentation
Filling of defects of endodontic origin
Mandibular reconstruction
Repair of traumatic defects of the alveolar ridge, excluding maxillary and mandibular fracture
Filling of resection defects in benign bone tumors, benign cysts or other osseous defects in the alveolar ridge wall.

V. Substantial Equivalence

Documentation is provided which demonstrates PROGENIX™ DBM Putty to be substantially equivalent to previously cleared bone void fillers such as PROGENIX™ DBM Putty (Medtronic Sofamor Danek, K072265, SE 1/9/2008), PROGENIX™ DBM Putty (Medtronic Sofamor Danek, K060794, SE 12/18/06), DBX Demineralized Bone Matrix Putty and Paste (Musculoskeletal Transplant Foundation, K040501, SE 04/29/05), Accell Connexus™ DBM Putty (IsoTis, OrthoBiologics, Inc., K060306, SE 03/27/2006), Intergo® Oral (Biomet 3i, K070147, SE 05/14/2007), and GRAFTON® DBM (Osteotech, Inc., K051188, SE 01/03/2006).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 13 2008

Ms. Michelle Obenauer
Regulatory Affairs Supervisor
Medtronic Sofamor Danek USA
1800 Pyramid Place
Memphis, Tennesse 38132

Re: K080462
Trade/Device Name: PROGENIX™ DBM Putty
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: NUN
Dated: February 12, 2008
Received: February 20, 2008

Dear Ms. Obenauer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K080462

1 of 1

510(k) Number (if known): K080462

Device Name: PROGENIX™ DBM Putty

Indications for Use:
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Filling of cystic defect

Filling of extraction sites

Filling of lesions of periodontal origin

Craniofacial augmentation

Filling of defects of endodontic origin

Mandibular reconstruction

Repair of traumatic defects of the alveolar ridge, excluding maxillary and mandibular fracture

Filling of resection defects in benign bone tumors, benign cysts or other osseous defects in the alveolar ridge wall.

Prescription Use ____X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K080462